Dynatronics
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K120835
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AUG 20 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

16 August 2012

SUBMITTED BY: DYNATRONICS CORPORTATION
7030 Park Centre Drive
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SUBMITTERS NAME: Douglas Sampson
VP, Operations and R&D
DYNATRONICS CORPORATION

1. DEVICE NAME:

Trade Name(s):	Dynatron® ThermoStim™
Common Name:	Combination Electrical Stimulation and Thermal Therapy probe
Classification:	Class II
Regulation Nos:	882.1320, 890.5720
Product Codes:	GXY, ILO

2. PREDICATE DEVICES:

Dynatron Solaris™ series Ultrasound probe in combination mode - K031329 (October 22, 2003)

ArTek Spot® thermal probes – Exempt (hot/cold pack) from ThermoTek, Inc.

3. DESCRIPTION:

The Dynatron ThermoStim probes are used to provide therapeutic electrical stimulation and thermal therapy treatments. The probes consist of a handle with a treatment head and connections for a lead wire and/or circulating water. The probes act as an electrode for therapeutic electrical current provided by a Dynatron Solaris device, or other similar Dynatronics electrical stimulation devices in the delivery of electrical stimulation therapy. The treatment head transfers thermal energy (hot or cold) from circulating water when connected to a Dynatron QUAD7™.

The probes are a passive, manual therapy accessory. Treatment cycles are controlled through previously cleared Dynatronics electrical stimulation and QUAD7 devices.

There are two versions of the probe face – a flat head with a surface area of 11.4 cm^2 (1.5" diameter) and a domed head with a surface area of 12.3cm^2 (1.1" diameter).

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4. INDICATIONS FOR USE:

A hand held cutaneous electrode to be used with Dynatronics Solaris devices to apply electrical stimulation and apply heat and cooling to the skin

The Indications for Use stated herein are consistent with the cleared indications for the predicate device.

5. TECHNICAL ANALYSIS:

The Dynatron ThermoStim probes generate therapeutic benefits as described in allowed claims through the delivery of electrical stimulation and thermal therapy to targeted tissues.

The probes allow the practitioner to manually apply various electrical stimulation treatments (limited to modalities available from the FDA cleared Dynatronics Solaris series devices) as well as thermal therapy (hot or cold). The delivery of hot thermal energy has a target value of 110° Fahrenheit and the cold thermal energy has a selectable target value from 37 – 50° Fahrenheit.

Performance Characteristics

There are two treatment face options with the Dynatron ThermoStim probes. Both utilize the same handle and connections to therapy delivery devices. The treatment faces differ in that one is a 1.1" dome with 12.3 cm^2 surface area and the second is a 1.5" flat with 11.4 cm^2 surface area. Both probes act as an accessory to provide the following treatment options:

Biphasic, Russian, HiVolt, Interferential Current (IFC), Premodulated (IFC), and Microcurrent

Thermal therapy – Hot = 110° Fahrenheit
Cold = 37 – 50° Fahrenheit

Non-clinical Bench Testing

Wave forms were captured from a Dynatron Solaris device through the ThermoSTIM probe and the Ultrasound probe in combo mode. Analysis of the wave forms for delivery of electrical stimulation treatments show no differences between the two probes

ThermoSTIM probes were tested for dielectric strength per EN60601-1 and for electromagnetic compatibility per EN60601-1-2. The probes pass the applicable test limits associated with the Solaris electrical stimulation device.

Thermal data was collected using the ThermoSTIM probe in "hot" mode and delivering an electrical stimulation treatment. Treatments were delivered on two body parts per patient and using warm gel and room temperature gel. Results showed temperatures consistently between 104°F and 112°F.

6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

The Dynatron ThermoStim probes share the same basic characteristics, features and intended uses as the predicate probes and, therefore, are substantially equivalent to the Dynatron Combination probe (applicable "K' number listed above) and the exempt ArTek Spot thermal probes.

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7. SAFETY AND EFFECTIVENESS SUMMARY:

There are no substantive differences between the product defined in this 510(k) submission and the predicate devices. This device is similar to the technology that is currently used in other similar medical devices. This device is subject to development and documentation as required in the Quality System Regulation, 21 CFT Part 820, under design/change control, and is subject to verification and validation to applicable standards / guidance documents. The sum of bench test results and design control outcomes allows us to conclude that the Dynatron ThermoSTIM probes are as safe and effective in delivering treatments when used as indicated in specific applications under a clinician's supervision / therapy program as the predicate probes.

Signed: _____ Dated: _____

Douglas Sampson, VP, Operations and R&D
DYNATRONICS CORPORATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dynatronics Corporation
% Mr. Douglas Sampson
Vice President
7030 Park Centre Drive
Salt Lake City, Utah 84121

AUG 20 2012

Re: K120835
Trade/Device Name: Dynatron ThermoStim probe
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY, ILO
Dated: August 9, 2012
Received: August 10, 2012

Dear Mr. Sampson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ___K120835_____

Device Name: Dynatron ThermoStim probe

Indications for Use:

A hand held cutaneous electrode to be used with Dynatronics Solaris devices to apply electrical stimulation and apply heat and cooling to the skin

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120835